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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,859	01/16/2004	Paul M. Bjorndal	DE01047	8426
24265	7590	07/26/2005	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			BUNIN, ANDREW M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAL

Office Action Summary

Application No.

10/759,859

Applicant(s)

BJORNDAL ET AL.

Examiner

Andrew M. Bunin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-12, 15-17, and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanpher et al. (US 5333106). Lanpher et al. disclose a medication inhaler simulator including a housing 104 having a bore extending therethrough, and a mouthpiece 102 connected with said housing and being in open communication with said bore; and a control circuit for measuring pressure drop at a position below said mouthpiece (column 11, lines 65-68) (column 12, lines 1-10). The control circuit being below the mouthpiece can be defined as located towards the back of the device as shown in Figure 1B. The control circuit includes a pressure transducer 120 for producing an output signal corresponding to said pressure drop at said position, a display 130 for providing an indication of acceptable inhalation, and a microprocessor 124 connected with said display for controlling said display in response to said output signal from said pressure transducer and elapsed time. The medication inhaler simulator further includes an opening at 112 in a wall of said housing, and further including a conduit having one end connected with said wall of said housing at said opening and an opposite end connected with said pressure transducer 120, wherein said control

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circuit measures 114/116 said pressure drop at said opening as shown in Figure 1B.

Lanpher et al. also disclose the housing including a restriction arrangement 112 for restricting air passage through a portion of said bore to provide adjustment of a pressure drop through said bore. The pressure drop is adjusted by the diameter decreasing from the main chamber of the inhaler to the coupler section 112 as shown in Figure 1B. The opening in said housing is positioned between said restriction arrangement 112 and said mouthpiece 102 as shown in Figure 1B.

Lanpher et al. continues to disclose a control circuit including an analog-to-digital converter 122 connected between said pressure transducer 120 and said microprocessor 124 for digitizing said output signal prior to supply thereof to said microprocessor as shown in Figure 1B. The control circuit includes a start switch for closing a power circuit in order to supply power to said microprocessor from a power supply (column 22, lines 65-68) as shown in Figure 1A. This control circuit further includes a timer circuit 430 for opening said power circuit after a predetermined amount of time (column 23, lines 60-63) (column 24, lines 18-23).

Lanpher et al. further disclose a display 130 includes at least one lighting device, which is selectively caused to be illuminated by said microprocessor for providing an indication of both inhalation rapidity (time) and inhalation flow rate peak (volume over time) (Figures 4a-e and Figures 5a-c) (column 5, lines 47-52). In addition, at least one lighting device includes a plurality of light emitting diodes,

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and further comprising drivers 123 connected between said light emitting diodes and said microprocessor 124 (column 5, lines 13-17). Lanpher et al. continue to disclose at least one lighting device is arranged to display said inhalation rapidity and said inhalation flow rate peak in a bar graph form (Figures 5a-5c).

As for claims 19-23, Lanpher et al. display includes a lighting device, which is illuminated by said microprocessor 124 to provide a single display that indicates whether inhalation is acceptable (column 5, lines 18-21). This display is a function of values of both inhalation rapidity and inhalation flow rate peak. The single display includes a plurality of bars, which are selectively illuminated in dependence upon a single value calculated from the values of both inhalation rapidity and inhalation flow rate peak (Figures 5a-c). Lanpher et al. has also disclosed how different display bars are illuminated with different colors (column 6, lines 13-17). Lanpher et al. display indicates to user that inhalation rapidity and inhalation flow peak are above or below a threshold as shown in Figures 4a-e and Figures 5a-c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. Lanpher et al. discloses everything except the mouthpiece is removably mounted on said housing. It would have been obvious to one having ordinary skill in the art at the time of the invention to make the mouthpiece removable as well as threadedly mounted on said housing since it was known in the art that mouthpieces were capable of being removed from the inhaler through a thread connection to allow user to clean the mouthpiece after each use.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. Lanpher et al. disclose everything except the housing including a closed end covered by said mouthpiece. However, Applicant has failed to display the criticality in having the closed end covered by the mouthpiece. Lanpher et al. teaches a closed end including pressure sensing opening (between 112 and 114) positioned in front of the pressure transducer 120, and at least one air flow opening fluidly connected with an outside of said housing 104 via the mouthpiece 102. The housing 104 includes at least one recessed wall section at 112 positioned behind said at least one airflow opening at 102 (see Figure 1B).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Armer et al. (US 5954047). Lanpher et al. has taught everything except the recessed wall section including a curvature that reduces in depth in a radial dimension at an intermediate portion thereof to create an airflow restriction with said mouthpiece so as to create a venturi effect. However, Armer et al. teaches an inhaler with a recessed wall section 42 including a curvature

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that reduces in depth in a radial dimension at an intermediate portion thereof to create an airflow restriction with said mouthpiece so as to create a venturi effect. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Lanpher et al. as taught by Armer et al. to create a venturi effect in order to control fluid flow effectively.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Campbell (US 5640149). Lanpher et al. teaches everything except a voltage regulator. However, Campbell teaches a control circuit further including a voltage regulator (303, 306, and 307) connected with a power supply 301/302 through a power circuit, and which supplies a predetermined DC voltage to a microprocessor in response to power supplied by said power supply (column 4, lines 56-65). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Lanpher et al. with the addition of the voltage regulator taught by Campbell in order to control the amount of DC voltage to the microprocessor.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Arp (US 5165397). Lanpher et al. teaches everything except the control circuit also having a voltage detector. However, Arp teaches a control circuit including a voltage detector 95 connected with a microprocessor 275, for detecting voltage supplied by the power supply, and for sending a signal to said microprocessor when said voltage is below a predetermined value in order to prevent operation of said microprocessor (column 7, lines 37-54). Therefore, it would have been obvious to a person of ordinary skill in the art to

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modify Lanpher et al. with detector taught by Arp in order to alert/stop the microprocessor if the voltage falls below a specific threshold.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Strupat et al. (US 6358058). Lanpher et al. discloses everything except the lighting device includes a liquid crystal display. Strupat et al. teaches an inhaler-training device with a liquid crystal display (LCD).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use an LCD in order to display the bar graph results of a user's inhalation flow rate and inhalation rapidity.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. Lanpher et al. teaches everything except m equals five and n equals ten. However, the Applicant has failed to show any criticality in the specification for m equaling five and n equaling ten. Therefore, it would have been obvious matter of design choice to a person of ordinary skill in the art at the time of the invention to modify Lanpher et al. to obtain the invention as specified in claim 24.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. Lanpher et al. teaches everything except the control circuit being mounted within said housing and the housing including a viewing opening, and said display is positioned to be viewed through said viewing opening. At the time the invention was made, it would have been an obvious matter of design choice to a person ordinary skill in the art to place the control circuit within the housing and produce a viewing opening for the display

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because Applicant has not disclosed that mounting the control circuit in the housing and creating a viewing opening provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the control circuit separate from the housing and the display positioned separate from the housing as taught by Lanpher et al. Therefore, it would have been an obvious matter of design choice to modify Lanpher et al. to obtain the invention as specified in claims 25 and 26. In addition, it has been held that forming in one piece an article, which has formerly been formed in two pieces and put together, involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893).

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Nowacki et al. (US 4796614). Lanpher et al. teaches everything except mouthpiece including a one-way valve. However, Nowacki teaches a mouthpiece 72 including a one-way valve 90 to inhibit contamination of said housing if a patient exhales into the mouthpiece. In addition, the one-way valve 90 includes a retainer having openings mounted in said mouthpiece, and a flexible valve flap mounted on said retainer which moves away from said retainer to permit air flow through said retainer and said mouthpiece during inhalation and which blocks said openings in said retainer during exhale by the patient through the mouthpiece (see Figure 5) (column 4 and column 5, lines 61-68 and lines 1-15).

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Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanpher et al. in view of Holroyd (US 6553988). Lanpher et al. discloses everything except a closure cap removably positioned over said mouthpiece. However, Holroyd teaches a closure cap 510 removably positioned over said mouthpiece 405, an actuation assembly in said housing for being capable of actuating start switch upon removal of said closure cap (column 5, lines 53-67) (See Figure 1). In addition, the actuation assembly includes a ring 500 mounted for rotation in said housing, said ring including an actuating projection for being capable of actuating said start switch upon rotation of said ring, and a first engaging portion 530; and a second engaging portion 520 mounted to said closure cap for engagement with said first engaging portion to rotate said ring 500. Holroyd continues to teach said second engaging portion 520 is formed on an inner surface of said closure cap 510 so as to rotate said ring 500 in a first direction upon removal of said closure cap and to rotate said ring in a second direction upon threaded insertion of said closure cap on said housing (column 5, lines 53-67) (column 6, lines 45-50). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Lanpher et al. with the cap actuation device taught by Holroyd in order to quickly actuate the system when the mouthpiece cap is taken off inhaler. Holroyd and Lanpher et al. teach everything except the housing including external threads and said closure cap includes internal threads for threadedly positioning said closure cap on said housing in covering relation to said mouthpiece. However, it would have been obvious to one having ordinary skill in the art at the time of the invention was

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made to use a threaded connection since it was known that threading was well known in the art for tightening a cap over a mouthpiece to keep it securely fastened. Lastly, Holroyd and Lanpher et al. also don't teach said first engaging portion extends outwardly of said housing through at least one opening in a wall of said housing. However, Applicant has failed to specify the criticality for this portion extending outward from the housing in the specification. Therefore, it would have been an obvious matter of design choice to modify Lanpher et al. in view of Holroyd to obtain the invention as specified in claim 31.

As for claims 32-41, the method steps would have been obvious by the use of the device outlined in claims 1, 10, 11, 15, 17, 19, 21, 22, 23, and 24.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5447150, US 4981295, US 3991304, US 6626843, and US 4984158.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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